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| 10/581,173                    | 01/23/2007                          | Jerome Cassayre      | 70312/UST           | 1639             |
| 86344<br>Syngenta Cror        | 7590 06/30/200<br>Protection, Inc., | EXAMINER             |                     |                  |
| Patent and Tra                | demark Department                   | KLINKEL, KORTNEY L   |                     |                  |
| 410 Swing Ro<br>Greensboro, N |                                     |                      | ART UNIT            | PAPER NUMBER     |
|                               |                                     |                      | 1611                |                  |
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|                               |                                     |                      | 06/30/2009          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

#### Application No. Applicant(s) 10/581,173 CASSAYRE ET AL. Office Action Summary Art Unit Examiner Kortney L. Klinkel 1611 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 17 April 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

| 4)⊠ Claim(s) <u>1-16</u> is/are pending in the application.               |
|---|
| 4a) Of the above claim(s) 1-8 and 10 is/are withdrawn from consideration. |
| 5) Claim(s) is/are allowed.   |
| 6)⊠ Claim(s) <u>9 and 11-16</u> is/are rejected.                          |
| 7) Claim(s) is/are objected to.   |
| 8) Claim(s) are subject to restriction and/or election requirement.       |
| Application Papers  |

# 9) The specification is objected to by the Examiner.

|            | Applicant may not re | equest that any obje  | ction to the dra | wing(s) be he    | d in abeyance.  | See 37 CFR 1     | .85(a).        |        |
|------------|----------------------|-----------------------|------------------|------------------|-----------------|------------------|----------------|--------|
|            | Replacement drawing  | ng sheet(s) including | the correction   | is required if t | he drawing(s) i | s objected to. S | ee 37 CFR 1.12 | 21(d). |
| 11)        | The oath or declar   | ation is objected to  | by the Exam      | niner. Note th   | e attached O    | ffice Action or  | form PTO-152   | 2.     |
| Priority u | ınder 35 U.S.C. §    | 119                   |                  |                  |                 |                  |                |        |

# 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of:

10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner.

Certified copies of the priority documents have been received.

 Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

| Attachment(s)  |   |  |
|--|---|--|
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Paper No(s)Mail Date 1/23/2007. | Interview Summary (PTO-413)     Paper No(s)Mail Date.     Neline of Informal Pater LApplication.     Other: |  |
| C. Datastand Vandamark Office  |   |  |

#### DETAILED ACTION

#### Claims

Acknowledgement is made of the amendments and remarks filed 7/2/2008. Claims 12-16 were newly added. Claims 4, and 6 were amended. Claims 1-16 are pending in the instant Office action.

#### Election/Restrictions

The following restriction was required in telephone conversation with applicant's representative William Teoli on 6/15/2009.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, drawn to a method of combating and controlling pests.

Group II, claims 9-16, drawn to compounds and compositions.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The common technical feature linking the claims is compounds of generic formula (I). This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. In the present case, Bonjouch et al.

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(Tetrahedron, 1986, 42(24), 6693-6702, as per Applicant's IDS), teach compounds of formula (I), see p. 6696, compound 14 as one example. As a result, no special technical features exist among the groups because the inventions in Groups I-IV fail to make a contribution over the prior art. In conclusion, Groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept, and therefore, restriction for examination purposes as indicated is proper.

During a telephone conversation with William Teoli on 6/26/2009 a provisional election was made without traverse to prosecute the invention of Group II, drawn to compounds and compositions, claims 9-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

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requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant's election with traverse of the species III-3, which is the compound wherein R2 is 2-chloro-pyrid-4-yl, n = 0, Ra = H, p and q are 2, and R8 is 4-chlorocinnamyl, in the reply filed on 7/2/2008 is acknowledged. Acknowledgement is also made of applicant's election with traverse of the species of pest "insects" in the reply filed on 4/17/2009. This species election applies only to Group I drawn to a method of combating and controlling various pests. Because applicant elected Group II, drawn to compounds and compositions in a telephone conversation on 6/26/2009, this species election is rendered moot.

Claim 10, drawn to a compound of formula II wherein R8 is hydrogen or tertbutoxycarbonyl, is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking

claim. Election was made with traverse in the reply filed on 7/2/2008.

Claims 9, and 11-16 are under consideration in the instant Office action to the

extent that they read on the elected species, compound III-3, which is the compound

wherein R2 is 2-chloro-pyrid-4-yl, n = 0, Ra = H, p and q are 2, and R8 is 4-

chlorocinnamyl.

Information Disclosure Statement

Acknowledgement is made of applicant's submitting an information disclosure

statement on 1/23/2007. The submission is in compliance with the provisions of 37

CFR 1.97. Accordingly, the information disclosure statement has been considered by

the examiner.

Foreign Priority

Acknowledgment is made of applicant's claim for foreign priority based on an

application filed in the United Kingdom on 12/12/2003. It is noted, however, that

applicant has not filed a certified copy of the 0328909 application as required by 35

U.S.C. 119(b).

Specification

The lengthy specification has not been checked to the extent necessary to

determine the presence of all possible minor errors. Applicant's cooperation is

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requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because of the following informalities: Currently the specification lists two different Table 1's, one on page 16 and one on page 114. Throughout the document from page 41 through page 113 reference is made to the substituents as defined in Table 1. It appears as of Table 1 on page 114 should be Table 2. If this is the case, then current Table 2 at page 115 needs to be renamed and properly referred to as Table 3.

Schemes I and II are listed using Roman numerals, but Schemes 3 and 4 use Arabic numbers.

Appropriate correction is required.

#### Claim Objections

Claim 14 is objected to because of the following informalities: A period is missing at the end of the claim. Appropriate correction is required.

### Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 9, and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9 and 11-16 recite a compound of formula (I') or salts or N-oxides thereof. There is insufficient written description for these limitations. Applicant has not described any examples of salts or any N-oxides that may be useful in the instant invention. Page 3 merely recites "salts or N-oxides thereof". Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." Enzo Biochem. Inc. v. Gen-Probe Inc., 296 F.3d 316.

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1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle* & Co., 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicants describe no salts of N-oxides that might be useful in the present invention and thus have not described this genus in a manner that would allow one skilled in the art to immediately envisage the compounds contemplated for use in the claimed compositions. As such, the claims lack adequate written description for the claimed "salts or N-oxides thereof" other than those agents discussed supra.

Claims 9, and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the species III-3, which is the compound wherein R2 is 2-chloro-pyrid-4-yl, n = 0, Ra = H, p and q are 2, and R8 is 4-chlorocinnamyl, does not reasonably provide enablement for all the compounds of formula (I'). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make and use** the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include, but are not limited to:

(A) The breadth of the claims;

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- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art:
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure

All of these factors have been considered with the most relevant ones discusses below.

The nature of the invention and the breadth of the claims. The nature of the invention is directed to compounds of formula (I') as well as an insecticidal, acaricidal or nematicidal composition comprising an insecticidally, acaricidally or nematicidally effective amount of a compound of formula (I'). The instant claims are directed to a large number of compounds, with considerably different substituents attached thereto. Therefore, the breadth of the claim is very large. Below is a recitation of the possible options for just one of the 10 variables present in the structure of formula (I') from claim 9:

R1 is hydrogen, optionally substituted alkyl, optionally substituted alkoxycarbonyl, optionally substituted alkylcarbonyl, aminocarbonyl, optionally substituted alkylcarbonyl, aminocarbonyl, optionally substituted alkylaminocarbonyl, optionally substituted aryl, optionally substituted heteroaryl, optionally substituted aryloxy, optionally substituted heteroaryloxy, optionally substituted heterocyclyoxy, cyano, optionally substituted alkenyl, optionally substituted alkynyl, optionally substituted cycloalkenyl, optionally substituted heterocyclyl, optionally substituted alkylnyl, optionally substituted heterocyclyl, optionally substituted alkylnyl, optionally substituted heterocyclyl, optionally substituted alkylnyl, optionally substituted alkylnyl, optionally substituted alkylnyl, optionally substituted aryl, optionally substituted aryl, optionally substituted aryl, optionally substituted heterocyclyl or R13 and R14 together with

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the N atom to which they are attached form a group -N=C(R16)-NR17R18; R15 is H, optionally substituted alkyl, optionally substituted alkoy, optionally substituted aryl, optionally substituted aryloxy optionally substituted heteroaryl, optionally substituted heteroaryloxy or NR19R20; R16, R17 and R18 are each independently H or lower alkyl; R19 and R20 are independently optionally substituted alkyl, optionally substituted aryl or optionally substituted heteroaryl;

The definition of R1 alone represents an innumerable number of possible options, especially when one considers with what the various groups can be optionally substituted based on the definitions provided beginning at page 3 of the instant specification. Several of the substituents that are the group which optionally substitutes the above listed functionalities can be further optionally substituted. As can be seen, this series of optional substitutions having optional substitutions, and so forth and so on...is infinite.

The state of the prior art and the predictability or lack thereof in the art. The state of the prior art is such that the biologically active compounds function in a lock and key mechanism and the structure of the compound has to be specific in order to carry out the desired function. Even a difference of a methyl group verses a hydrogen can change the properties of a compound altogether. A good example is theophylline verses caffeine. They differ by just a methyl group but one of them has a pharmaceutical use as a bronchodilator. There is no reasonable predictability and no established correlation between the different substitutions on a core that they would all behave in the exact same way. In fact 3-(1-acetyl-4-piperidinyl)-1-acetylindoline, which falls within the genus of compounds claimed, and differs from the elected species in the substitutions

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off both nitrogen atoms has antiallergic activity rather than pesticidal activity. See Ueda et al. preparation 22 (EP0224919, as per applicant's IDS). The state of the art also involves screening against various pests to determine which compounds exhibit the desired activities against which pest. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any biologically active compound on its face.

The amount of direction or guidance present and the presence or absence of working examples. The specification describes by structure hundreds of thousands of compounds in tables I through CCLXVIII (195,104 compounds to be exact). Pages 116 through 120, Schemes I through 4, generically describe the synthesis of the compounds. More specifically, Scheme I shows how to chemically modify the indolenitrogen atom, Scheme II is directed to chemically modifying the 3-position of the indole ring with a pyrrolidine or pyridine ring. Scheme 3 is directed to a combination of chemically modifying the 3-position of the indole ring with a pyridine ring moiety, followed by chemically modifying the indole nitrogen, followed by functionalizing the pyridine nitrogen with an R8 group. Scheme 4 is directed to a synthesis of compounds of formula I where R2 and R3 are groups other than hydrogen. From these schemes it is clear that the synthesis of the various molecules is highly dependent upon those materials that are readily available either commercially or through relatively straight forward chemical synthesis. It is highly doubtful that the synthetic methods described in the specification are capable of describing the synthesis of all those compounds

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currently encompassed by generic formula (I') in the claims. For example, it is doubtful that based off the direction and guidance of the specification that one of ordinary skill in the art would be able to, without undue experimentation, synthesize a compound of formula (I') wherein the indole ring is substituted with one chloride, one cyano, one group R21R22N, wherein R21 and R22 are hydrogen, one cyclohexyl group which is further substituted with a hexyl group. Furthermore, it is doubtful that even some of the less exotic compounds encompassed by formula (I') could be synthesized. The reactions set forth in Schemes I through 3 (scheme 4 does not apply here because formula (I') specifies that R2 and R3 are both hydrogen), require that the "starting" indole (i.e. compound (4), (3), (2), etc.) not have too many reactive functionalities, or the subsequent reactions will not work. For example if a compound of formula (4) in Scheme I contains R4 groups which can be deprotonated with a base and/or are nucleophilic, these R4 groups will react with the electrophile and/or L-R8 group. Accordingly, applicant has not sufficiently shown how to make a representative set of the innumerable compounds encompassed by formula (I').

Furthermore, Applicants have not provided any competent evidence or disclosed tests to suggest that a representative set of compounds have utility, let alone utility as pesticides. Pages 139 and 140 provide data for the elected species III-3, as well as for roughly a dozen other compounds against *Spadoptera littoralis*, tobacco budworm, diamond back moth, two-spotted spider mite, yellow fever mosquito and *Aedes aegypti*. Of the compounds tests, not every compound is effective against every pest. Applicant provides no guidance or discussion of the mechanism of action for the various claimed

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compounds. Therefore it is unclear which compounds will be effective against which pests. Due to the lack of predictability in the art with respect to structural/functional relationships, it is unlikely that all the recited compounds will have utility as pesticides. For example, substituting some of the hydrogen atoms on the elected species III-3 for more polar substituents such as nitro and/or fluorine will drastically change the electronics and therefore the solubility and efficacy of the resulting compound.

The quantity of experimentation needed. Given the large genus of compounds encompassed by the claims, the lack of specific guidance with regard to which compounds will retain functional activity, the lack of a representative set of data, and the lack of predictability in the art, it will require undue and unpredictable experimentation in order to make and use the recited invention as currently claimed.

Genetech Inc. V. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which pests can be controlled by which compounds encompassed in the instant claims, with no assurance of success. Thus, rejection of claims under 35 U.S.C. \$112, first paragraph, is deemed proper.

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#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonjouch et al. (Tetrahedron, 1986, 42(24), 6693-6702, as per Applicant's IDS).

Banjouch et al. teaches compounds 14-15 (p. 6701) which anticipate the claimed compounds. Compound 14 has the below structure, see also page 6696. Compound 15 has the same structure shown below with an additional oxo in the 2-position of the piperidyl ring.

With respect to claim 11 which recites, an insecticidal, acaricidal or nematicidal composition comprising an insecticidally, acaricidally or nematicidally effective amount of a compound of formula I' as defined in claim 9, the phrase insecticidal, acaricidal or nematicidal composition is a recitation of the intended use for the claimed composition. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant situation, Banjouch et al. teach at

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page 6701 a composition comprising either compound 14 and 15 in a concentration of 14 and 16.8 mmol respectively. Page 112 of the instant specification states that a composition having from 0.0001 to 95% active compound is effective. Therefore because Banjouch et al. teaches a compound as required by the instant claims and the amount taught by Banjouch et al. falls within that amount which is taught in the specification to be effective, the compositions of Banjouch et al. would necessarily be insecticidal, acaricidal or nematicidal. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 9, and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (EP 0224919)

Ueda et al. teach 3-(1-acetyl-4-piperidinyl)-1-acetylindoline, of the below structure. See Preparation 22, pages 44-45.

With respect to claim 11 which recites, an insecticidal, acaricidal or nematicidal composition comprising an insecticidally, acaricidally or nematicidally effective amount of a compound of formula I' as defined in claim 9, the phrase insecticidal, acaricidal or

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nematicidal composition is a recitation of the intended use for the claimed composition. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant situation, Ueda et al. teach in Preparation 22 a composition comprising the above compound in a concentration of approximately 22 mmol (based on a molecular weight of the above compound of 286.37 q/mol and a final reaction yield of 32q). Page 112 of the instant specification states that a composition having from 0.0001 to 95% active compound is effective. Therefore because Ueda et al. teaches a compound as required by the instant claims and the amount taught by Ueda et al. falls within that amount which is taught in the specification to be effective, the compositions of Ueda et al. would necessarily be insecticidal, acaricidal or nematicidal. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

#### Conclusion

Claims 9 and 11-16 are rejected. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Kortney Klinkel whose telephone number is (571)270-

5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

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KI K

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611